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| 09/743,107      | 08/21/2001  | Lars A. Hanson       | 003300-723          | 5780             |

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EXAMINER

KAM, CHIH MIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1653

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/743,107

Applicant(s)

HANSON ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 54-98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-98 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>0404</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                              |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

1. The finality of the previous Office Action is withdrawn because of a new ground of rejection.

#### ***Status of the Claims***

2. Claims 54-98 are pending.

Applicants' amendment filed April 12, 2004 is acknowledged, and applicants' response has been fully considered. Claims 87 and 88 have been amended. Therefore, claims 54-98 are examined.

3. The formal drawings of Figs 2, 4A and 4C filed April 12, 2004 are acknowledged.

#### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 112***

4. The previous rejection of claims 87-97, under 35 U.S.C.112, first and second paragraphs, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 9-10 in the amendment filed April 12, 2004.

#### ***Sequence Listing***

5. In the Sequence Listing, the description of SEQ ID NOs: 92, 97, 98 and 99 indicates a lactam bond is formed between position 5 (e.g., Xaa is Gln, Lys, Orn, Ala or Nle for SEQ ID NO:99) and position 9 (e.g., Xaa is Arg or Lys for SEQ ID NO:99), although Lys, Orn or Arg is at 5 or 9 position, there is no Glu or Asp residue at either position, thus it is not feasible to form such a bond, appropriate corrections are required. The description of SEQ ID NOs :47, 48, 49, 50, 51 and 102 is not consistent with the listed sequence, e.g., the description indicates SEQ ID NO:47 is corresponding to the sequence consisting of amino acids 21-30 of human lactoferrin

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with one amino acid being substituted, however, SEQ ID NO:47 has the same amino acid sequence as the natural peptide (SEQ ID NO:38), appropriate corrections are required.

Applicant must comply with the requirements of sequence rules (37 CFR 1.821-1.825) to include all the sequences in the sequence listing and to identify each sequence with a "SEQ ID NO:".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 54-98 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 54-98 are directed to a peptide comprising SEQ ID NO:99 (Cys-Phe-X<sub>1</sub>-X<sub>2</sub>-X<sub>3</sub>-X<sub>4</sub>-X<sub>5</sub>-X<sub>6</sub>-X<sub>7</sub>-Lys-Val-Arg), wherein X<sub>1</sub>, X<sub>2</sub>, X<sub>3</sub>, X<sub>4</sub>, X<sub>5</sub> and X<sub>6</sub> are defined, and wherein SEQ ID NO:38 is excluded; a medicinal product or a food stuff comprising the peptide; and a method of treating infections or inflammations comprising administering the peptide. The specification indicates that the new peptides are formed of the sequences constituted of all or some of the amino acids 12-40 of human lactoferrin counted from the N-terminal end, and preferably modified versions thereof, these peptides described in the sequence listing are fungicidal and bactericidal (pages 2-4); and the peptide may be modified so that the residue Lys in position 5 in SEQ ID NO: 6 and Asp in position 9 are linked by the formation of a lactam between the side

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chains of the residues, thus forming a loop (page 6, line 37-page 7, line 2). The specification further asserts that SEQ ID NO: 99 has a lactam bond formed between position 5 (Xaa is Gln, Lys, Orn, Ala or Nle) and position 9 (Xaa is Arg or Lys) in the sequence listing. However, the specification has not indicated the peptides of SEQ ID NO:99 does not have a lactam bond. The lack of description of SEQ ID NO:99 without a lactam bond as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 54-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54-98 are indefinite because claim 54 recites SEQ ID NO:99 with only X<sub>1</sub>, X<sub>2</sub>, X<sub>3</sub>, X<sub>4</sub>, X<sub>5</sub> and X<sub>6</sub> defined, it does not indicate the lactam bond formed between positions 5 and 9 as indicated in the description of SEQ ID NO:99 of the sequence listing, however, since there is no Glu or Asp at position 5 or 9, it is not feasible to form lactam bond, therefore it is not clear whether the peptide contains the lactam bond. Claims 55-98 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

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8. Claims 68-71 are indefinite because the claim does not further limit the length of the peptide, e.g., claim 55 recites the peptide is SEQ ID NO: 70, 72-74, 80-83, 87-91, 93-95 or 97, while claim 68, for example, recites the peptide "comprising" SEQ ID NO: 70 or 74.

***Conclusion***

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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May 13, 2004

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
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